

Clinical Success of Defecation-Inducing, Gravity-Fed, Colonic Lavage for Relief of Constipation - Report of 1,804 Procedures

Christopher South¹, Benjamin D. Havemann², Reed B. Hogan³, Orly Levitan⁴, Kevin Cronly¹

¹Ohio Gastroenterology and Liver Institute, Cincinnati, OH, USA.

²Austin Gastroenterology, Austin, TX, USA.

³Gastrointestinal Associates and Endoscopy Center, Jackson, MS, USA.

⁴Hygieacare Inc., Norfolk, VA, USA.

**Corresponding Authors: Christopher South, Ohio Gastroenterology and Liver Institute, Cincinnati, OH, USA.*

Abstract

Chronic Constipation (CC) is a global health problem associated with considerable morbidity and significant financial burden. This problem is one of the top five most common physician diagnoses for gastrointestinal disorders among outpatient clinic visits, accounting for almost eight million ambulatory visits a year. Current therapies for CC are costly and often produce suboptimal results. We report on a prescription-only gravity-fed colonic lavage procedure that provides an alternative for patients suffering from constipation. This FDA-cleared open system using high-volume (average 40 liter) gravity-fed water. We report on 1,804 consecutive procedures performed under stringent standard operating procedures (SOP) for 1,040 patients under general supervision by 81 physicians between January 2017 and March 2021 (51 months). All the constipation relief procedures were 100% clinically successful, and no serious adverse events were recorded. Clinical success was defined as successful defecation. Data was collected by the staff and by providing the patients with multiple-choice questionnaires and free-text post-procedure surveys. Adverse events were recorded by the staff using a standardized process. The patients' age range was 18-99, with the mean age 57.2±17, 81% females and 19% males. Of the 1,040 patients, 76% (792 patients) had one procedure, and 24% underwent multiple procedures (4.02±4.8). The post-procedure surveys revealed high patient satisfaction and willingness to repeat at all clinic locations. High-volume, gravity-fed, defecation-inducing colonic lavage for constipation relief is shown to be safe and effective and should be considered a primary medical alternative for patients suffering from constipation who have failed or are unsatisfied with other therapeutic alternatives.

Keywords: Constipation, Motility

INTRODUCTION

Constipation is a global health problem associated with a significantly decreased quality of life and financial burden among outpatient, affecting 14% of adults worldwide¹. Constipation is one of the five most common diagnoses reported by physicians for patients presenting with gastrointestinal disorders². Chronic constipation (CC) is recognized as a common gastrointestinal (GI) disorder. Stool frequency, consistency, appearance and shape are

key terms for description and typically characterized by and associated with incomplete evacuation and straining^{3,4,5}. Acute severe constipation may cause intestinal obstruction and may even require surgery⁶. Constipation places a significant mental, physical, and financial burden on patients, who suffer from a significant loss of productivity and lower quality of life⁷. The prevalence of CC in adults is estimated as 16%-17% of the population worldwide, and 33.5% in adults aged 60 to 101 years⁸, with women and elderly patients more likely to suffer⁹.

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Treatments for patients suffering from constipation include hydration, nutrition, exercise, biofeedback, over the counter (OTC) and prescribed laxatives^{10,11}. The monthly cost of laxatives alone can reach \$245 while often yielding sub-optimal results^{7,12,13}. Prescription only laxatives can cost approximately \$300-500 for a 30-day supply¹⁴. The annual estimated costs for OTC laxatives and physician visits are \$821 million. Nearly 50% of patients express dissatisfaction with conventional constipation therapies¹⁵. Physician visits due to constipation account for eight million physician visits annually in the United States. The annual direct costs for constipation in the US are estimated to exceed \$230 million¹⁶ and the costs incurred by women with constipation are double that of women without¹⁷. Constipation may also increase the risk of colorectal cancer (CRC)¹⁸, and CC patients are at risk for an inadequate bowel preparation for colonoscopy¹⁹, which can decrease CRC detection rates, further increasing the economic burden of these patients.

The Hygieacare System is an FDA cleared and prescription-only system used for the management of patients with constipation. HygiRelief[®], a procedure for high-volume gravity-fed colonic lavage with induced defecation, provides a non-medication alternative for patients suffering from constipation. We present the clinical outcomes from 1,040 patients that underwent 1,804 HygiRelief procedures, including patient satisfaction and feedback.

METHODS

Gravity-fed Colonic Lavage, with Induced Defecation, for Constipation Relief

The gravity-fed colonic lavage with induced defecation is FDA-cleared and intended for use under physician supervision. This procedure, called HygiRelief[®], has been proven safe and effective as a medication-free constipation relief by Hygieacare Inc.²⁰. It is performed by trained personnel using stringent standard operating procedures (SOPs) under physician supervision. In this procedure, the patient is seated on the disinfected basin, and a sterile, disposable, rectal catheter is inserted approximately 3cm into their rectum. Thirty-five or more liters of twice filtered water (37°-39°C) flows into the bowel using a gravity-

fed delivery system, loosening the stool, inducing defecation, and allowing the patient to evacuate their colon. The water flow is automatically stopped if the water temperature exceeds the range of 37°-39 °C.

Collection and Statistical Analysis of Demographic and Clinical Information

A retrospective analysis of data was performed on de-identified clinical and demographic information of patients who received the gravity-fed colonic lavage with induced defecation for constipation relief. The procedures were performed between January 2017 and March 2021 in centers in Austin, TX, Jackson, MS, Cincinnati, OH, and Norfolk, VA. The demographic and self-reported clinical information were collected via patient questionnaires and staff documentation. Staff at each center documented adverse events (AE) occurring during the procedure. The AEs included nausea, vomiting, dizziness, and abdominal cramping, all of which were minor. The severity of these events was recorded on a scale of 1-4; where 1= "Very little", 2= "Some", 3="Quite a bit", and 4="A lot". Since this is a retrospective descriptive review of a standard FDA-cleared and unchanged approved procedure, de-identified and with patient consent, no IRB was required for this study.

Satisfaction Reports and Free Text Analysis

To assess patients' satisfaction, all patients were provided with a post-procedure satisfaction survey that included four questions referring to the quality of the gravity-fed, defecation-inducing, colonic lavage experience and one question asking about the patients' willingness to repeat the procedure. The answers to the survey questions were ranked 3-0 where: definitely agree=3, agree= 2, disagree= 1, and definitely disagree= 0. The patients' survey responses were analyzed by counting responses in each category for each of the centers, and the results are presented per rating and satisfaction percentages. In addition, the patients were given an open-ended question to express their opinion on the procedure. Patients' feedback was available for 33% of the procedures, gathered from all four sites. The patients responses were analyzed for word abundance. Data is presented as a Word Cloud analysis where the size of the words represents their relative abundance in the patients' responses.

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RESULTS

Clinical Analysis and Outcome

In the period between January 2017 and March 2021, 1,040 patients underwent 1,804 procedures. Clinical success, defined by defecation, was recorded in all procedures. The average procedure length was 74 minutes and an average of 40 liters of double filtered

and temperature-controlled water were infused. Patients' age ranged from 18 to 99, with an average of 57 ± 17 . Seven percent of the patients were < 30 years, 50% of the patients were < 60 years old, and 8% of the patients were > 80 years old (Figure 1). Of the procedures with a recorded gender, 19% were performed on male, and 81% were performed on female patients. Table 1 summarizes demographic data and key results.

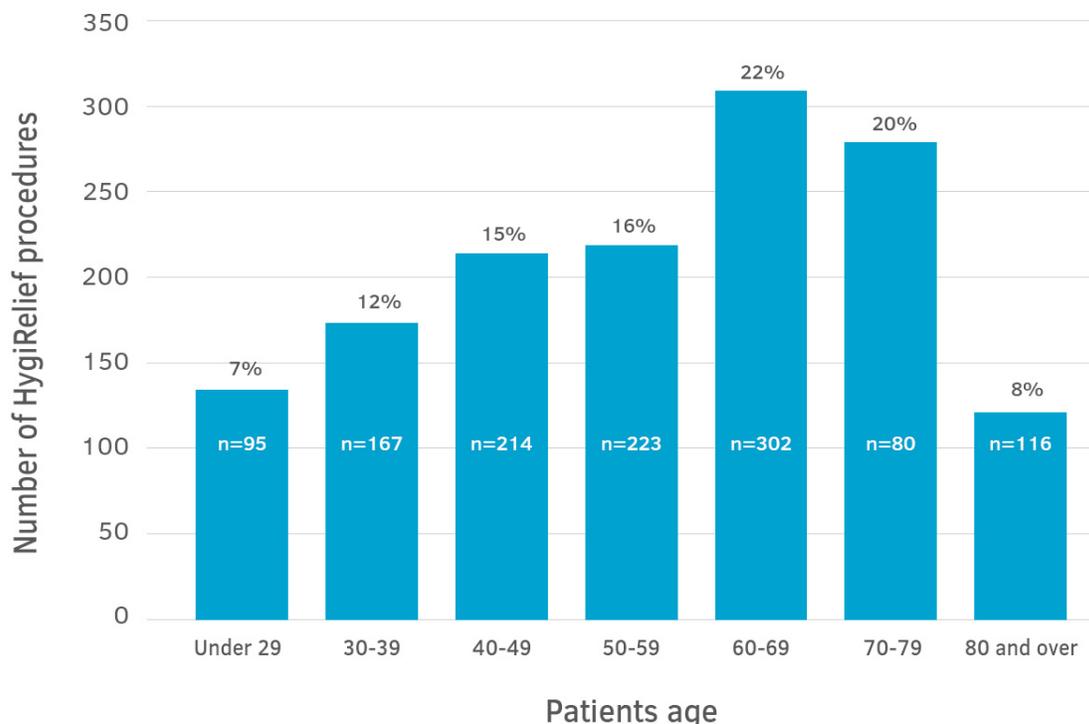


Figure 1. HygiRelief patients divided by age group. The percentage of each age bracket from the overall population is presented on top for the blue bars.

Table 1. Key demographics and summary of key results. All patients underwent HygiRelief between January, 2017 and March, 2021.

Parameter	Summary of demographic data and key results
Procedures performed	1,804
Number of patients	Total - 1,040 Patients that have had only one procedure- 792 Patients that have had multiple procedures - 248
Number of prescribing physicians	81
Age of patients	min - 18; max - 99; average- 57 ± 17 (recorded in n=1,392 procedures)
Gender of patients	Male - 205 (19%) Female - 858 (81%) (recorded in n=1,063 procedures)
Serious adverse events	0

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There were no serious adverse events recorded for any of the 1,804 procedures. For minor AEs, 6.5% of the procedures were reported to have had some level of nausea, where 2% reported "Very little", and only 0.4% reports "A lot". Vomiting was recorded for less than 1.5% of procedures, and dizziness was recorded in 2.4% of the procedures altogether. Abdominal cramping was recorded in 16% of the total procedures, where 2% were recorded as "Very little", 8% as "Some", 4% as "Quite a bit", and only 2% as "A lot" (Table 2).

Table2. Analysis of adverse effects as experienced by patients following the HygiRelief procedure. Symptoms were self-reported.

	Very little	Some	Quite a bit	A lot	None
Nausea	2% (n=30)	3% (n=62)	1% (n=25)	0.4% (n=7)	93.4% (n=1,716)
Vomiting	0.4% (n=7)	0.4% (n=8)	0.3% (n=6)	0.2% (n=3)	98.7% (n=1,816)
Dizziness	0.8% (n=15)	1% (n=18)	0.4% (n=7)	0.2% (n=4)	97.6% (n=1,796)
Abdominal pain/cramping	2% (n=38)	8% (n=139)	4% (n=71)	2% (n=35)	82% (n=1,557)

Patient Acceptance and Satisfaction

Twenty-four percent of the patients (n=248) underwent multiple visits during the study period, with an average of four visits per patient, and a maximum of 36 visits for one patient. The number of repeat procedures (done on a patient following their first visit) increased from 52 in 2017 to 251 in 2019 and 246 in 2020, despite the overall slow-down of the COVID-19 pandemic (Table 3, Figure 2). Of the 248 patients who underwent multiple 750 procedures, 199 patients received two to four procedures, 31 patients underwent 5 to 10 procedures, and 18 patients

received more than 10 procedures for relief of chronic constipation, each (Figure 3). Of the procedures performed during the study period, 5% were done on patients younger than 29 (n=34), 11% on patients age 30-39 years old (n=81), 12% on patients age 40-49 (n=88), 15% on patients age 50-59 (n=112), 24% on patients age 60-69 (n=171), 24% on patients age 70-79 (n=173), and 9% on patients over the age of 80 (n=65). The Patients' self-reporting indicates that the procedure prompted relief that can be sustained up to four weeks and improves their quality of life during the following weeks.

Table3. HygiRelief procedures on new and returning patients performed between January 2017 and March 2021, divided by year.

Year	2017	2018	2019	2020	2021 (up to March)
Total procedures	166	317	548	591	182
Procedures done on new patients (% from total)	114 (69%)	202 (64%)	297 (54%)	345 (58%)	96 (53%)
Procedures done on returning patients (% from total)	52 (31%)	115 (36%)	251 (46%)	246 (42%)	86 (47%)

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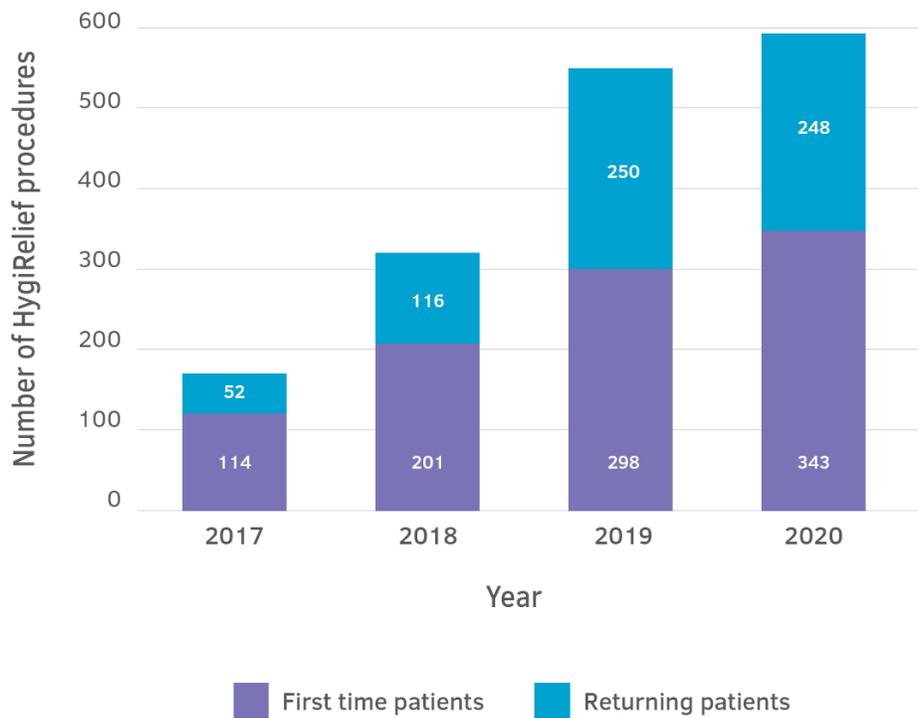


Figure2. HygiRelief procedures performed on new and returning patients between January 2017 and December 2020 divided by year. First time patients are in purple, returning patients in blue.

248 patients had 750 HygiRelief procedures

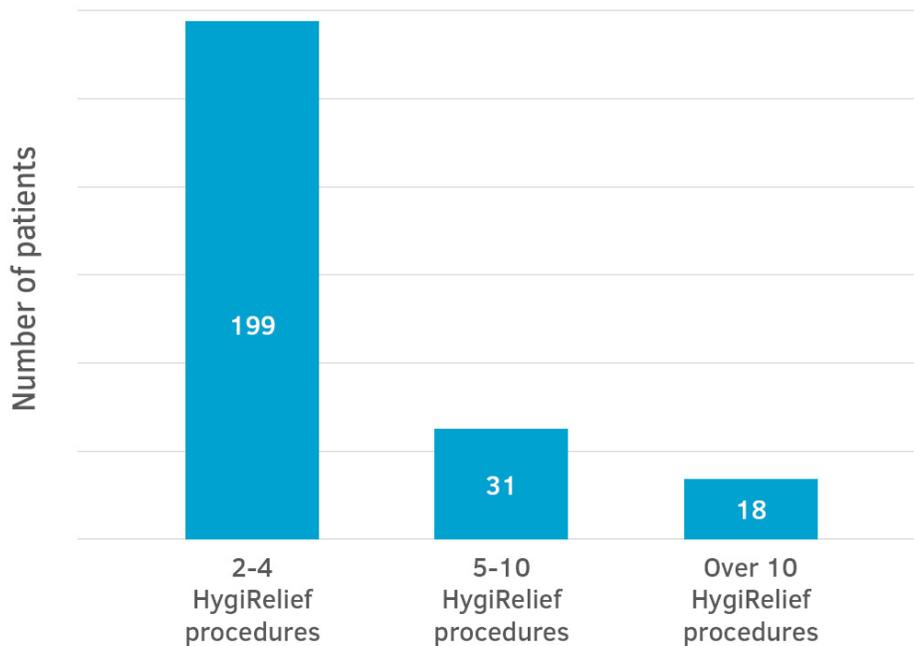


Figure3. Returning HygiRelief patients divided by the number of procedures they underwent between January, 2017 and March, 2021 (n=248).

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Patients were given post-procedure questionnaires to assess how satisfied they were from the treatment center and the procedure itself. Patient satisfaction (on a 3-0 scale, n=895) was 2.96 for “efficient check-in”, 2.97 for “clear explanation”, 2.98 for “technician availability”, and 2.98 for “room cleanliness” (Table 4). Patients were also asked to provide free-text

comments. Analysis of 588 answers revealed that the most abundant words were positive with “very” (n=219) and “great” (n=171) being the most common words (Figure 4). The phrases “will be back” and “so much better” repeated 42 and 24 times in the patients’ written feedback, repeatedly.

Table4. Analysis of patient’s quality of service survey following the HygiRelief. Patients were asked to rate parameters on a 3-0 scale, where: “definitely agree” =3, “agree”=2, “disagree”=1, and “definitely disagree”=0. n=895. Satisfactory percentage represents the percent of patients that rated ≥2.

Satisfaction parameter	Satisfactory percentage (Score, 3-0)
Efficient check-in	98.6% (2.96±0.2)
Clear explanation	99.0% (2.97±0.2)
Technician availability	99.3% (2.98±0.1)
Room cleanliness	99.3% (2.98±0.2)



Figure4. Open text analysis of free-text comments by patients (n=598). Word size represent the abundance of the specific word in the patients’ comments.

DISCUSSION

In this retrospective clinical study, high-volume gravity-fed colonic lavage with induced defecation (HygiRelief®) is shown to be a well-tolerated, safe,

and effective therapeutic treatment for patients with constipation. All the procedures were categorized as successful, indicating that this procedure is agnostic to the specificity of constipation and underlying

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diseases. There were no serious adverse events (AEs), and minor AEs were minimal (Table 2). The procedure had high patient satisfaction and showed a significant willingness for patients to repeat (Table 4, Figure 4). Physician acceptance is reflected by the growing number of new and repeated procedures prescribed to the patients (Table 3, Figures 2 and 3).

Constipation places a significant mental, physical, and financial burden on patients. These patients suffer from a significant loss of productivity and lower quality of life⁷. Finding the appropriate solutions for a patient with CC imposes a significant overall cost burden to the US healthcare system. Impacted patients impose an economic burden on the healthcare system and overload the already overpopulated emergency department. The success of the HygiRelief procedure, yielding defecation in all patients referred by their physician for relief, suggests that this approach can be particularly helpful to patients.

HygiRelief has been shown to be safe, fast, agnostic to the cause of constipation, and has physician acceptance and outstanding patient satisfaction. In view of the sustained relief achieved by patients, we suggest that high-volume, gravity-fed colonic lavage with induced defecation under physician supervision should be considered as a viable therapeutic option for patients with constipation who have failed or are unsatisfied with lifestyle and other therapeutic options.

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